



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,307	02/13/2002	Hartmut Strobel	04734.0004	4483

5487 7590 08/11/2004

ROSS J. OEHLER
AVENTIS PHARMACEUTICALS INC.
ROUTE 202-206
MAIL CODE: D303A
BRIDGEWATER, NJ 08807

EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,307	STROBEL ET AL.	
	Examiner	Art Unit	
	Deepak R Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 ~~9~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11, 18-20 and 24-48 ~~9~~ are allowed.
- 6) ☒ Claim(s) 12-17 ~~9~~ are rejected.
- 7) ☒ Claim(s) 21-23 ~~9~~ are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the communication filed on April 26, 2004.

Claims 1-48 are pending in this application.

The following rejections are withdrawn:

The rejection for claims 1-4, 6-9, 11-15 and 17-20 under 35 U.S.C. 102(b) over Beasley et al., WO 97/04775 is withdrawn in view of applicant's arguments. Applicant submits that the bicyclic ring depicted in formula (I) of the reference cannot be an aromatic ring and R⁵ in instant claims must be an aromatic heterocyclic group.

The rejection for claims 6-9 and 11 under 35 U.S.C. 102(b) over Horn et al., EP 420064 is withdrawn in view of applicant's arguments. Applicant submits that the reference does not teach that the compounds can be used in a method to stimulate the expression of endothelial NO-synthase in a mammal.

The rejection for claims 6-11 under 35 U.S.C. 102(b) over Yamada et al., WO 00/51970 is withdrawn in view of applicant's arguments. Applicant submits that the reference does not teach that the compounds can be used in a method to stimulate the expression of endothelial NO-synthase in a mammal.

The following rejections are maintained:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1624

1. Claims 12-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Horn et al., EP 420064 for the reasons provided in the previous office action which are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that the reference does not teach every element of the present claims. However, the reference clearly teaches the use of the compounds in a method of treating sexual dysfunction by administering a therapeutically effective amount of the compound. Thus, the reference teaches the administration of the same compounds to the same patient population. Applicant argues that the reference does not provide that the compounds could stimulate the expression of endothelial NO-synthase in the mammal. This is not found to be persuasive because as explained above, the reference teaches the administration of the compounds to a mammal to achieve several therapeutic benefits including sexual dysfunction. Whether the administered amount of the compound possesses the recited activity of mode of action, the reference compound is used in achieving the same therapeutic benefit. The instant claims recite a mode of action of stimulating the expression of endothelial NO-synthase, which is a property inherently possessed by the compounds of the reference. The reference compounds inherently possess this biological property particularly because the reference compounds are also administered in the same therapeutic application. The properties possessed by the compounds, whether explicitly or inherently, can not be separated from the compounds itself.

Art Unit: 1624

2. Claims 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al., WO 00/51970, for the reasons provided in the previous office action which are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that Yamada nowhere teaches the stimulation of the expression of endothelial NO-synthase. However, the reference clearly teaches the use of the compounds in a method of treating diseases, e.g., stroke, by administering a therapeutically effective amount of the compound which is the same therapeutic benefit achieved by the instantly claimed method. Thus, the reference teaches the administration of the same compounds to the same patient population. Applicant argues that the reference does not provide that the compounds could stimulate the expression of endothelial NO-synthase in the mammal. This is not found to be persuasive because as explained above, the reference teaches the administration of the compounds to a mammal to achieve several therapeutic benefits including stroke. Whether the administered amount of the compound possesses the recited activity of mode of action, the reference compound is used in achieving the same therapeutic benefit. The instant claims recite a mode of action of stimulating the expression of endothelial NO-synthase, which is a property inherently possessed by the compounds of the reference. Reference compounds inherently possess this biological property particularly because the compounds are used in the same therapeutic applications as recited in the instant claims. The properties possessed by the compounds, whether explicitly or inherently, can not be separated from the compounds itself.

Allowable Subject Matter

Claims 1-11, 18-20 and 24-48 are allowed. Claims 21-23 are objected to as being dependent upon a rejected claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

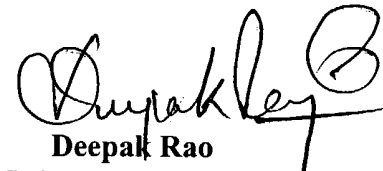
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-

Art Unit: 1624

0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Deepak Rao
Primary Examiner
Art Unit 1624

August 8, 2004